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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

HY-VEE, INC., Plaintiff, v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC. and LUPIN LTD., Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Case No.**

Plaintiff Hy-Vee, Inc. ("Plaintiff" or "Hy-Vee") brings this civil action against Defendants Bausch Health Companies Inc. ("Bausch"), Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc. (collectively "Salix"), Santarus, Inc. ("Santarus"), Assertio Therapeutics, Inc. ("Assertio"), Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively "Lupin," and with Bausch, Salix, Santarus and Assertio, "Defendants") under the antitrust laws of the United States. For its Complaint, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by a purchaser of Glumetza, a brand-name prescription drug marketed by Bausch and used by patients with Type 2 diabetes to prevent and

control high blood sugar. Plaintiff seeks overcharge damages and other relief arising out of Defendants' unlawful foreclosure of generic competition in the market for Glumetza and its AB-rated generic equivalents.

2. The active ingredient in Glumetza is metformin. Prescription metformin has been available as a generic drug since 2002. Defendant Assertio developed an extended-release version of metformin that can alleviate some of the drug's common side effects. Assertio obtained several patents on the extended-release technology and began selling extended-release metformin, marketed under the brand name Glumetza, in 2005. Extended-release mechanisms are very common, however, and Assertio's patents were weak and narrow and could not prevent competition from generic versions of the drug.

3. The effects of generic competition for a brand drug are predictable: sales switch quickly from the brand drug to the generic version. Generic drugs are priced at a fraction of the brand drug price, with prices for the generics falling farther as more generics enter the market, and purchasers shift swiftly to the generics. Brand manufacturers' profits fall dramatically upon generic entry. Forestalling generic entry, then, is the name of the (unlawful) game.

4. When Defendant Lupin developed a generic Glumetza, Assertio and its marketing partner, Defendant Santarus, sued Lupin for patent infringement. That lawsuit triggered an automatic prohibition on Lupin's entry into the market for 30 months. Just before the end of the 30 months when Lupin would have been able to enter the market with generic Glumetza, Assertio/Santarus and Lupin settled the patent lawsuit.

5. Assertio/Santarus paid Lupin to delay generic entry. The companies settled the patent litigation in February 2012 with a "reverse payment." That is, Assertio/Santarus, the Plaintiff in the patent lawsuit, paid Lupin, the defendant in the patent lawsuit the reverse of a typical settlement payment. The payment took the form of a no-authorized generic ("no-AG") agreement in which Assertio/Santarus agreed that, when Lupin finally did enter the market in 2016, for at least six months, they would not compete against Lupin by marketing their own generic version of Glumetza. In return, Lupin agreed to stay out of the market from 2012 to February 2016.

6. Those Defendants allocated the Glumetza market between them: Assertio/Santarus got the entire market from 2012 to February 2016, and Lupin got the generic sector of the market from February 2016 until at least August 2016. That market-allocation agreement is blatantly unlawful under federal antitrust law.

7. Other generic manufacturers could have upended the Assertio/Santarus/Lupin anticompetitive scheme. The Assertio patents' weakness created the risk that another manufacturer could avoid them and market generic Glumetza before February 2016. To prevent that possibility, Assertio/Santarus and Lupin included in their agreement two deterrent provisions aimed at other competitors: (a) if another generic manufacturer succeeded in entering the market before February 2016, Lupin could also enter on that earlier date; and (b) Assertio/Santarus would not grant a license to any other manufacturer to enter the market sooner than 180 days after Lupin entered.

8. These deterrents ensured that, no matter how many resources another manufacturer might expend in overcoming Assertio's patents, it could never get the financial reward of being the first and only generic manufacturer on the market. It could not get that reward by winning a patent lawsuit against Assertio/Santarus because such a win would trigger Lupin's right to enter earlier; it could not get that reward by negotiating an earlier-entry license from Assertio/Santarus because the terms of the settlement agreement expressly prohibited such a license.

9. Assertio/Santarus and Lupin unlawfully closed every pathway to generic competition before February 2016. Lupin agreed not to enter before then, and the deterrents eliminated the incentive for other generic manufacturers to try to enter before then. And, Defendants extended the anticompetitive effect beyond February 2016—Assertio/Santarus agreed that they would not compete in the generic sector from February 2016 until at least August 2016, and agreed not to grant a license to any other generic to compete during that time.

10. In short, Assertio/Santarus and Lupin agreed to maintain a monopoly in the sale of Glumetza and its generic equivalents where monopoly shouldn't—and wouldn't—have existed under lawful, competitive practices.

11. That monopoly was extremely valuable, and Assertio/Santarus wasted no time in exploiting it. In November 2013, Santarus announced that it was being acquired by Defendant Salix for $2.6 billion. At the time, Glumetza accounted for just under half of Santarus' sales. From 2012 to 2015 Assertio/Santarus and Salix raised Glumetza prices by more than 40%, far outstripping the 4.2% rise in the Consumer Price Index.

12. In April 2015, when Glumetza accounted for more than 25% of its sales, Salix in turn sold the Glumetza monopoly to Valeant Pharmaceuticals, Inc. (now known as Bausch Health). Valeant paid $14.5 billion to acquire Salix.

13. Valeant was known in the industry as a ruthless and remorseless exploiter of drug-product monopolies. As Forbes magazine later characterized it, Valeant's business strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees…." Nathan Vardi & Antoine Gara, *Valeant Pharmaceuticals' Prescription for Disaster*, Forbes, April 13, 2016, https://www.forbes.com/sites/nathanvardi/2016/04/13/valeant-pharmaceuticals-prescription-for-disaster/#6f4f657f206c. "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary." Industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned." Bethany McLean, *The Valeant Meltdown and Wall Street's Major Drug Problem*, Vanity Fair, Summer 2016, https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

14. Within four months of acquiring the Glumetza monopoly, Valeant *raised the price an additional 750%*. The price of a 30-day supply skyrocketed from $350 to more than $3,000. In the half year before the price hike, Salix made $145 million on Glumetza; in the half year after, Valeant made more than $800 million.

15. Piling injury on injury, the unlawful agreements also resulted in an extraordinarily high price for the generic product when Lupin finally entered the market in February 2016. Valeant complied with the unlawful agreement not to compete in the generic sector, and Lupin took full advantage. With no competition in the generic sector and branded Glumetza being sold

at an astronomically high price, Lupin sold a 30-day supply of generic Glumetza for more than $2,200. Lupin made more than $650 million in profits on generic Glumetza in 2016 alone.

16. Plaintiff brings this action to recover overcharge damages already suffered and to obtain equitable relief to stop the ongoing harm.

II. JURISDICTION AND VENUE

17. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15(a) and § 26, and seeks to recover threefold damages and other relief for the injuries sustained by Plaintiff resulting from Defendants' unlawful restraint of trade and maintenance of monopoly power in the market for Glumetza and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

18. Defendants transact business within this district, and they carry out interstate trade and commerce in substantial part in this district and/or have an agent and/or can be found in this district. Venue is therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1407.

III. PARTIES

19. Plaintiff Hy-Vee, Inc. is an Iowa corporation having its principal place of business at 5820 Westown Parkway, West Des Moines, Iowa 50266. Hy-Vee owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Glumetza. Hy-Vee brings this action on its own behalf and as the assignee of Topco Associates, LLC ("Topco"), a group purchasing organization of which Hy-Vee is a member. Topco in turn holds an assignment of claims from McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which during the relevant period purchased Glumetza directly from Bausch for resale to Hy-Vee and other Topco members. By virtue of McKesson's assignment to Topco and Topco's reassignment to Hy-Vee, Hy-Vee is the owner and assignee of McKesson's claim for overcharges arising out McKesson's purchases of Glumetza that was subsequently resold to Hy-Vee during the period from November 16, 2012 through January 30, 2020.

20. Defendant Assertio Therapeutics, Inc. ("Assertio") is a corporation organized under the laws of Delaware with its principal place of business located at 100 South Saunders Road, Suite 300, Lake Forest, Illinois. Until August 14, 2018, Assertio was named Depomed, Inc., which was a party to the unlawful agreements alleged herein. Assertio is the owner or licensee of the relevant patents.

21. Defendant Santarus, Inc. ("Santarus") is a corporation organized under the laws of Delaware and, during much of the relevant time, had its principal place of business in San Diego, California. Its current principal place of business is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Pursuant to a Commercialization Agreement signed in August 2011, Assertio granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States. Santarus was a party to the unlawful agreements alleged herein. On January 2, 2014, Santarus was acquired by defendant Salix Pharmaceuticals, Ltd. and became a wholly owned subsidiary of Salix Pharmaceuticals, Inc.

22. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Salix Pharmaceuticals, Inc. joined and adhered to the unlawful agreements alleged herein. Salix Pharmaceuticals, Inc. is a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.

23. Defendant Salix Pharmaceuticals, Ltd. is a corporation organized under the laws of Delaware with its principal place of business located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Effective January 1, 2014, Salix Pharmaceuticals, Inc. and Salix Pharmaceuticals, Ltd. ("Salix") assumed Santarus's rights and obligations under its Commercialization Agreement with Assertio. Salix Pharmaceuticals, Ltd. joined and adhered to the unlawful agreements alleged herein.

24. On April 1, 2015, Salix was acquired by Valeant Pharmaceuticals International, Inc., which, on or about that date, assumed Santarus's and Salix's rights and obligations under the Commercialization Agreement with Assertio. Valeant Pharmaceuticals International, Inc. joined and adhered to the unlawful agreements alleged herein. Effective on July 13, 2018, Valeant

Pharmaceuticals International, Inc. changed its corporate name to Bausch Health Companies Inc. Salix Pharmaceuticals, Ltd. is now a wholly owned subsidiary of Bausch Health Companies Inc.

25. Defendant Bausch Health Companies Inc. ("Bausch") is a corporation organized and existing under the laws of British Columbia, Canada with its U.S. headquarters located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Bausch joined and adhered to the unlawful agreements alleged herein.

26. Defendants Santarus, Salix, and Bausch are collectively referred to as "Valeant."

27. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia with its principal place of business located at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals is a wholly owned subsidiary of Defendant Lupin Ltd. and was a party to the unlawful agreements alleged herein.

28. Defendant Lupin Ltd. is a company organized under the laws of India with its principal place of business located at B/4 Laxami Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India, and was a party to the unlawful agreements alleged herein.

29. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

IV. REGULATORY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace.

30. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of

products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

31. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Lidoderm, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

32. Assertio/Santarus and other brand pharmaceutical sellers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

33. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs.

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

35. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer must list in the Orange Book any such patents that issue after the FDA approves the NDA within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

36. The FDA relies completely on the brand manufacturer's truthfulness in submitting patents to be listed, as it does not have the resources or authority to verify the validity or relevance of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments.

37. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the

same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to a generic drug that is therapeutically equivalent to a brand-name counterpart.

38. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

39. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

40. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications.

41. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

42. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

43. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When there is only one generic on the market, the generic price is lower than the branded price, but much higher than the price after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when

there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

44. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

45. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of the 180-day period of generic market exclusivity. This tactic is called exclusivity "parking." It creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

46. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

47. Under the "failure to market" provision, a first ANDA applicant forfeits 180- day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

48. Brand manufacturers and first-filing generics can structure their settlements to intentionally skirt these forfeiture provisions. For example, manufacturers can subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants must obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a Paragraph IV litigation.

49. In addition, brand and generic manufacturers can structure their settlements to provide the generic with180 days of de facto exclusivity even when it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions, e.g., the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. The brand can provide this result by agreeing not to license any other generic to enter the market any earlier than six months after the generic that has forfeited exclusivity has entered. Unless a subsequent generic is itself able to overcome applicable patent and regulatory

exclusivities, such an agreement will have the effect of de facto restoring the first generic filer's lost statutory exclusivity. This results in a windfall to the generic and a subversion of the regulatory scheme. Because the FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that confer de facto exclusivity – even where it has been forfeited de jure under the MMA – dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180 day period. And, because the lion's share of the generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

E. The Benefits of Generic Drugs.

50. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Assertio/Santarus as a grave threat to their bottom lines.

51. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

52. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that result from generic competition.

53. Generic competition enables Plaintiff and McKesson to purchase generic versions of the drug at substantially lower prices.

54. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices without losing substantial sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements at issue here.

F. The Impact of Authorized Generics.

55. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day exclusivity period. Such a generic is called an "authorized generic" and is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

56. In its study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales and reduce the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

57. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiff benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

58. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drugs at the same intervals and at the same rate at which they raised the price of the drugs prior to generic entry.

59. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to a generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such agreements deprive drug purchasers such as Plaintiff of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company has agreed not to sell an authorized generic, they eliminate competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

60. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer no-AG agreements to cash payments because, in the case of no-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition.

Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

V. OPERATIVE FACTS

A. Background

61. The active ingredient in Glumetza is metformin hydrochloride. For decades, metformin has been one of the most commonly prescribed oral medications for the treatment of Type 2 diabetes. It improves glycemic control.

62. On June 3, 2005, the FDA approved Assertio's NDA for Glumetza 500 mg and 1000 mg extended-release tablets, with an indication as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes.

63. Glumetza's extended-release formulation was designed for patients experiencing issues with the efficacy of immediate-release metformin products. Doctors often found it difficult to titrate patients up to the maximum daily recommended dose of 2000 mg of metformin due to the occurrence of gastrointestinal ("GI") side effects, such as nausea. Some estimates state that up to 50% of metformin-treated patients report GI side effects, and many of those unable to tolerate the effects failed to achieve adequate glycemic control.

64. Glumetza's extended-release mechanism works by causing the pill, once ingested into the stomach, to swell with water. The increased size serves the dual purpose of blocking the drug's exit from the stomach while steadily controlling the drug's release over the course of hours. This ensures the drug's release will occur in the stomach or upper GI tract, rather than the lower GI tract, thereby reducing the risk of GI side effects.

65. Glumetza was thus uniquely positioned in the market to offer patients with Type 2 diabetes an ability to reach their optimal dose of metformin with fewer GI side effects.

66. Under the NDA, Assertio listed several patents in the Orange Book for which it was the owner or licensee. For the 500 mg Glumetza product, Assertio listed the following patents:

Patent No.	Expiration
6,340,475 ('475 patent)	9/16/2016
6,635,280 ('280 patent)	9/16/2016
6,488,962 ('962 patent)	6/20/2020
6,723,340 ('340 patent)	10/25/2021

67. For the 1000 mg Glumetza product, Assertio listed in the Orange Book the following patents:

Patent No.	Expiration
6,488,962 ('962 patent)	6/20/2020
7,780,987 ('987 patent)	3/23/2025
8,323,692 ('692 patent)	3/23/2025

68. In October 2008, Santarus began promoting Glumetza under an exclusive-promotion agreement with Assertio. In August 2011, Santarus and Assertio entered into a new Commercialization Agreement pursuant to which Santarus became the NDA owner and assumed broader commercial, manufacturing, and regulatory responsibilities, including exclusive rights to manufacture and commercialize Glumetza in the United States.

69. Under the agreement, Santarus assumed sole decision-making authority on pricing, contracting, and promotion for Glumetza. Santarus also had the exclusive right to commercialize authorized-generic versions of the drug.

70. Under the Commercialization Agreement, Santarus agreed to pay Assertio a gradually increasing royalty rate (reaching a ceiling of 34.5% by 2015) on net sales of Glumetza before generic Glumetza entry. In the event of generic Glumetza entry, the parties agreed to equally share proceeds based on a gross margin split.

71. In addition, the Commercialization Agreement provided that Assertio would manage any patent-infringement lawsuits relating to patents covering Glumetza, subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. The parties agreed to split the costs of any patent lawsuit, with Santarus responsible for 70%, and Assertio responsible for 30%.

B. Bausch's Narrow Patents on Glumetza Could Not Prevent Generic Competition

72. Glumetza's patent protection was particularly narrow. The patents did not purport to claim metformin. Nor did they purport to claim a pharmaceutical formulation (e.g., tablet, capsule, injection) of metformin alone or the method of using metformin alone to treat diabetes. The drug substance had long been used in pharmaceutical formulations to treat Type 2 diabetes. Instead, all of Glumetza's patents related to oral dosage forms that provide extended, controlled release of a drug such as metformin.

73. The patents further did not purport to broadly claim controlled-release technology. That technology was developed in the 1970's and has since been used in a variety of applications. Controlled-release technology typically involves a polymeric formulation, which is a large molecule composed of repeating structural units, using either "reservoir" or "matrix" systems.

74. In a reservoir system, a core containing the active drug is coated with an acrylic polymer composition to help achieve extended release.

75. In a matrix system, the drug is dissolved or dispersed throughout the polymer and then formulated into a pill. After the patient swallows the pill, gastric fluids cause the matrix to swell to a size large enough to maintain the dosage form in the stomach during the fed mode, i.e., after a meal. This water-swollen polymeric matrix controls the rate at which the drug is released from the dosage form.

76. Glumetza's patents focus on a narrow range of formulations and methods that require a matrix controlled-release system. Assertio's patents did not even purport to invent the matrix system for metformin. There were many prior-art options for extended-release matrix delivery vehicles targeting the stomach, including: (i) a solid matrix formed of a substance that absorbs gastric fluid and swells as it absorbs fluid to extend gastric retention of the delivery vehicle, such as disclosed in U.S. Patent No. 5,007,790, "Sustained-Release Oral Drug Dosage Form," issued April 16, 1991; (ii) a matrix that limits the rate at which the surrounding gastric fluid diffuses through the matrix, reaches the drug, dissolves the drug, and diffuses out again; and (iii) a matrix that slowly erodes, continuously exposing fresh drug to the surrounding fluid, such as disclosed in U.S. Patent No. 4,915,952, "Composition Comprising Drug, HPC, HPMC, and PEO," issued April 10, 1990.

77. Glumetza's patents narrowly pertained to a particular type of water-swollen polymeric matrix that is responsible for controlled drug delivery. Glumetza's patents require, among other things, particular drug-release rates, drug-to-polymer ratios, dosage forms of particular sizes and shapes and duration, the use of specific polymers in sufficient quantities to perform the required functions, and specific manufacturing processes. One or more of these claim limitations define each of the purported inventions.

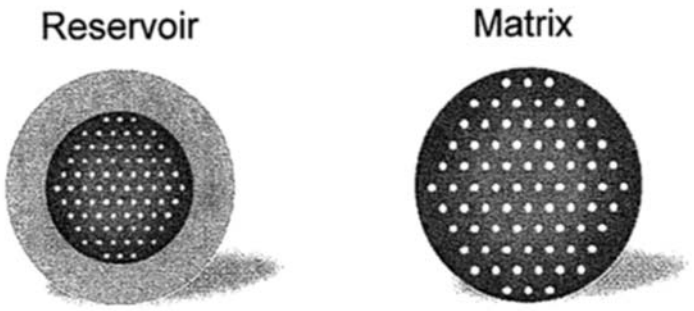
78. Assertio, as the party asserting infringement, would have the burden of proving that the generic manufacturer's product falls within every limitation of an asserted patent's claim; a generic manufacturer would prevail if its product fell outside even just one limitation of each asserted claim.

79. Generic manufacturers could avoid infringing—they could "design around"—the patents by forgoing the "matrix system" altogether. They could instead use the entirely different "reservoir system," designed to provide controlled release of the drug without, for example, "substantially retain[ing] its size and shape without deterioration until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached or remaining substantially intact until substantially all of the drug is released." A generic version of Glumetza using such a reservoir system would necessarily fall outside all the relevant patents' claims.

80. As noted, the prior art already taught how to incorporate a reservoir system, defined as a core containing the active drug that is coated with an acrylic polymer composition to help achieve extended release. For example, U.S. Patent No. 4,954,350, "Pharmaceutical Formulations Containing Acrivastine," issued September 4, 1990, (the "PFCA patent") discloses controlled-release pharmaceutical formulations for oral administration of acrivastine (an anti-histamine) utilizing a core containing the drug coated with acrylic polymers. The PFCA patent specifically identifies a neutral polymer based on ethyl acrylate and methyl methacrylate, Eudragit E30D ("Eudragit"), as one of the commercially available acrylic polymers that can be used as a coating. The PFCA Patent also discloses other prior art references of delayed-release formulations

containing a core of other active ingredients coated with a polyacrylate insoluble that is dispersible in water, such as Eudragit.

81. In short, a pivotal difference between the matrix and reservoir systems is the rate-controlling mechanism. In a matrix system, the mechanism controlling the rate of drug release is the polymeric matrix. In a reservoir system, by contrast, the rate-controlling mechanism is a polymeric membrane encasing the drug core.



82. Although the FDA requires generics to meet certain standards of equivalence to the brand, it does not require the brand and generic to have identical controlled-release mechanisms. So long as the generic manufacturer can assure the FDA that its product releases the drug at a similar rate and to a similar extent as the branded reference drug (thereby establishing bioequivalence), the FDA will not block the generic's approval on the ground that it uses a different controlled-release mechanism, such as a reservoir system.

83. Lupin's use of a reservoir system avoided each of Assertio's patents listed in the Orange Book as identified above.

84. Assertio's '475 and '280 patents are based on the same initial patent application and thus disclose the same invention. Both patents require a controlled-release dosage form in which a "drug is dispersed in a polymeric matrix that is water-swellable." As the patents explain, "the swelling of the polymeric matrix ... achieves two objectives—(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it ... provide[s] multi-hour, controlled delivery of the drug into the stomach." In this way, "[t]he rate limiting factor in the release of drug is therefore controlled diffusion of the drug from the matrix."

Accordingly, the basic and purportedly novel properties of the '475 and '280 patents are the *polymeric matrix*'s ability to control the rate of drug release from the dosage form by swelling to promote retention in the stomach and having an erosion rate that is substantially slower than its swelling rate.

85. A reservoir system can achieve the desired controlled release without relying on a polymeric matrix having the properties required by the '475 and '280 patents. A reservoir system wraps the drug core with a separate polymer coat that contains distinct chemical properties and represents an insoluble, physical barrier. The rate-limiting factor in the release of the drug is controlled by diffusion through the polymer coat, not from the matrix, as required under the '475 and '280 patents.

86. Due to their narrowness, neither the '475 patent nor the '280 patent could prevent a generic Glumetza product from launching before those patents expired in September 2016. In addition, since they were listed in the Orange Book only for Glumetza's 500 mg strength, they clearly could not block approval of a generic Glumetza 1000 mg ANDA. Regardless, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and launching generic versions of Glumetza 500 and 1000 mg, especially ones using a reservoir system.

87. Use of a prior-art reservoir system also allowed a generic manufacturer to design around the remaining, later-expiring Glumetza patents.

88. The '962 patent merely purports to offer an improvement over the '475 and '280 patents and covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." In terms of avoiding infringement, the "consisting essentially of" claims of the '962 patent can be avoided either by a dosage form having a shape that differs from that claimed or by using a delivery vehicle that materially differs from that of a solid monolithic matrix. A generic manufacturer would avoid infringing the '962 patent simply by virtue of using a non-swellable polymer coat, rather than a matrix, which materially affects the dosage form to control the drug's release.

89. The '340 patent purportedly covered only the optimal material to be used in the matrix in order for it to control the drug's release. So, again, a generic manufacturer would easily avoid infringing the '340 patent by using the host of other available materials to carry the drug rather than the specific claimed matrix of poly(ethylene oxide) and hydroxypropyl methylcellulose, to control the drug's release.

90. Both the '987 and '692 patents disclose a dosage form requiring a controlled-release coating that must be prepared by "curing the coated oral dosage form at a temperature of at least 55° C" and must consist of a neutral ester copolymer, a polyethylene glycol, one or more hydrophilic agents, and a pharmaceutically acceptable excipient. A generic manufacturer would easily design around those patents' claims by applying a different prior art coating to control the drug's release.

91. The '987 and '692 patents, having been listed for only the 1000 mg Glumetza product, clearly could not block a generic Glumetza 500 mg ANDA. Regardless, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and marketing generic versions of Glumetza 500 and 1000 mg.

C. Assertio Sued Lupin, Whose Potential Competition Threatened Glumetza's Growing Sales

92. The active ingredient in Glumetza, *i.e.*, metformin, was not patent protected, and other acceptable delivery vehicles existed in the prior art. Lupin therefore recognized the opportunity to develop and market a competing generic Glumetza product substantially before Glumetza's patents expired.

93. On or about July 27, 2009, Lupin filed ANDA 91664 seeking FDA approval to manufacture and sell a generic version of Glumetza 500 mg and 1000 mg. Lupin's ANDA contained a paragraph IV certification to all applicable Glumetza patents. At the time, Assertio had listed in the Orange Book only the '475, '280, '962, and '340 patents for Glumetza.

94. On or about November 6, 2009, Lupin notified Assertio that Lupin had filed ANDA 91664, detailing why the relevant patents were both invalid and not infringed by Lupin's ANDA product.

95. On or about November 25, 2009, Assertio sued Lupin in the U.S. District Court for the Northern District of California, claiming infringement of the '475, '280, '962, and '340 patents. Assertio's timely lawsuit triggered the Hatch-Waxman Act's automatic 30-month stay of the FDA's approval of Lupin's generic product, measured from the date Assertio received Lupin's November 6, 2009 paragraph IV notice letter.

96. Assertio filed the patent infringement lawsuit against Lupin without regard to the lawsuit's merits. In fact, Assertio knew that there was an overwhelming likelihood that it would lose the patent litigation. Assertio's true purpose in bringing the lawsuit was to obtain the automatic 30-month hiatus from generic competition. Simply by filing the case, Assertio delayed FDA approval of Lupin's generic and prevented it from coming to market before May 6, 2012.

97. On January 29, 2010, Lupin filed its answer to Assertio's complaint, asserting that the manufacture, use, offer for sale, sale, or importation of its ANDA product would not infringe any valid and enforceable claim of the relevant patents.

98. As the litigation proceeded, Assertio dropped its claim of infringement relating to the '340 patent.

99. On August 26, 2011, Lupin provided supplemental interrogatory responses disclosing that its ANDA product does not and cannot infringe Assertio's patents because it uses a reservoir system rather than a polymeric matrix system to extend the drug's release.

100. Relying on key differences between its reservoir-system product and the matrix-system products claimed under the Glumetza patents, Lupin established that its product did not meet the patents' requirements that: (i) the product remain "substantially intact" until all of the drug is released; (ii) the product's drug core "substantially retain its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles" until "at least about 80% of the drug has been released after eight hours of immersion in gastric fluid"; and (iii) "the drug is released at a rate controlled by the rate of diffusion" out of the polymeric matrix.

101. Lupin further explained that its reservoir delivery system used a coating that included Eudragit to control the drug's release, rather than being controlled by the polymeric

matrix core as required by the Glumetza patents. As stated above, controlled-release delivery vehicles based on a coating containing acrylic polymers, such as Eudragit, were well known in the prior art.

102. On January 27, 2012, the FDA tentatively approved Lupin's ANDA, meaning that the only thing preventing final approval of Lupin's ANDA was the 30-month stay, which was set to expire in May 2012. Once the stay expired and the FDA granted final approval, Lupin would have been able to launch generic Glumetza at risk—before a final, non-appealable judgment in the patent case. The tentative approval thus signaled to Assertio and Santarus a significant risk that Lupin was just months away from launching a non-infringing AB-rated generic Glumetza. Moreover, even if Lupin waited until its victory in the trial, Lupin would have been likely to enter the market in late 2012 or early 2013 because the patent case was scheduled for trial in October 2012.

103. Lupin's introduction of generic Glumetza would have devastated Assertio/Santarus's bottom line. As of January 2012, Glumetza represented more than 50% of Santarus's sales.

104. Lupin was particularly likely to launch generic Glumetza at-risk. In September 2011, Lupin had launched at-risk a generic version of Fortamet. Like Glumetza, Fortamet consisted of 500 mg and 1000 mg extended-release tablets of metformin hydrochloride. And, Lupin had launched generic Fortamet shortly after expiration of that 30-month stay—exactly the same juncture that Lupin was then approaching in the Glumetza litigation.

105. Santarus and Assertio also knew that, if the litigation proceeded, the overwhelming likelihood was that the Lupin product would be found not to infringe the Glumetza patents. As alleged above, Lupin's generic used a reservoir system, which was not covered by Glumetza's patents. Lupin thus had an extraordinarily small likelihood that any at-risk launch would later subject it to liability for patent damages.

106. In short, Santarus and Assertio correctly believed that Lupin intended to begin marketing generic Glumetza in May 2012 unless the parties settled the patent litigation.

D. Assertio/Santarus Paid Off Lupin to Prevent the Risk of Competition

107. To avoid the substantial probability that Lupin would launch a non-infringing generic Glumetza either at risk or after prevailing in court, Assertio and Santarus decided to extend the period of Glumetza's supracompetitive profits by paying Lupin to withdraw its patent challenges and delay introducing generic Glumetza.

108. On February 22, 2012—just after Lupin's January 2012 tentative approval and shortly before the 30-month stay was to expire in May 2012—Assertio/Santarus and Lupin entered into an agreement whereby Lupin agreed to end its challenge to the Glumetza patents and substantially delay entering the market in exchange for a No-AG pact.

109. Under the agreement, Lupin agreed to refrain from entering the market with a generic Glumetza until February 1, 2016 (subject to the MFE and MFEP clauses discussed below). In exchange for Lupin's agreement to delay its entry for nearly four years, Assertio/Santarus agreed not to market an authorized generic Glumetza 500 mg and 1000 mg product, and not to license any other manufacturer to market such a product under Assertio's NDA, for one year after Lupin's entry into the market (the "No-AG Payment"). Valeant in fact refrained from entering the market with its authorized generic version of Glumetza until February 2017—a year after Lupin's entry.

110. The purpose and effect of the No-AG Payment was to induce Lupin to abandon its patent challenge and agree not to compete with a generic version of Glumetza until February 2016. Assertio/Santarus would not have agreed to the No-AG Payment without securing, in exchange, Lupin's agreement not to market a generic version of Glumetza until February 2016. Likewise, Lupin would not have agreed to a delayed February 2016 entry without securing, in exchange, Assertio/Santarus's commitment to the No-AG Payment.

111. Absent the No-AG Payment, Santarus had the incentive and ability to market an authorized generic version of Glumetza immediately upon (if not before) Lupin's entry. For example, Santarus launched an authorized generic simultaneously with the first filer's launch of generic Zegerid. A rational profit maximizing entity in Santarus's position would not forgo an opportunity to gain additional sales by marketing an authorized generic. Indeed, Santarus ensured

that its commercialization agreement with Assertio gave Santarus the right to launch a Glumetza authorized generic.

112. By giving up the unqualified right to earn profits from marketing its own authorized generic, Santarus enabled Lupin to make approximately twice the unit sales, at a much higher price, all at the expense of Plaintiff and other purchasers. The No-AG Payment thus served as substantial compensation for Lupin's agreement to delay its entry, and Lupin could not have obtained this payment or its equivalent even if Lupin had won the patent litigation against Assertio.

113. The No-AG Payment's value to Lupin is readily calculable using the known economics of the pharmaceutical industry. Assuming, conservatively, that the term of the No-AG clause extended only six months, and not a year as suspected, the valuation from Lupin's perspective is a matter of estimating the additional sales it expected to make during its first six months of marketing in 2016 compared to the sales it expected to make in the first six months of entry in 2012 when, without the benefit of the No-AG Payment, it would have faced competition from Santarus's authorized generic.

114. For 2012, annual sales of Glumetza were approximately $150 million. Six months (180 days) of brand Glumetza sales would generate revenue to Assertio/Santarus of $75 million ($150 million * 0.5).

115. During the six-month generic exclusivity period, brands typically lose 80% of their sales to generics.. Thus, Lupin would have reasonably expected generics to capture approximately $60 million worth of brand units during those six months ($75 million * 0.8).

116. In the absence of a No-AG Payment, Lupin would have expected two generics (its own, and Santarus's authorized generic) to be in the market during those 180 days. With two generics in the market, the average generic price is typically driven down to 50% or less of the brand price. Thus, while the two generics would still sell units worth $60 million at brand prices during those six months, the revenues generated by those sales would drop to $30 million ($60 million * 0.5).

117. In addition to lowering prices, the presence of an AG also means that sales are split between the ANDA filer and the AG. Thus, Lupin would have reasonably expected unit sales of the generic during the six months to be split (roughly evenly) between Lupin and the Santarus authorized generic. Thus, without a No-AG Payment, Lupin would have expected that its revenues during the six months would be at most $15 million ($30 million * 0.5).

118. With the anticompetitive no-AG pact, Lupin would have expected to fare far better financially. First, Lupin would make 100% (not 50%) of the generic sales in the first six months.

119. Second, Lupin would have expected to make those sales at a far higher price. When there is only one generic on the market, it typically sells at a 20% discount off the price of the brand, rather than a 50% or greater discount.

120. Third, Lupin would have expected that the brand sales revenue, driven by both increased unit sales and increased prices, would be far higher in 2016 than it was in 2012. Santarus had just recently assumed full responsibility for commercializing Glumetza. Its sales were quickly rising, having doubled in the first quarter of 2012 compared to the first quarter of 2011. Santarus had just hired 30% more sales representatives and rolled out a new promotional program, prompting analysts to predict very significant sales growth. Consequently, Lupin would have reasonably expected annual brand sales as of 2016 to be at least $200 million.

121. Thus, with a No-AG clause in place, Lupin would have reasonably expected the value of its generic Glumetza sales during the six-month period in 2016 to be at least $64 million ($200 [annual brand sales] *.5 [six months] * .8 [percent of sales taken by generic] * .8 [20% price discount]).

122. The value of the No-AG payment to Lupin was, at a minimum, the difference between the value of six months of marketing in 2012 with an authorized generic on the market, and six months of marketing in 2016 without an authorized generic on the market. That difference is $49 million ($64 – $15). The No-AG Payment's value to Lupin was far more than it could have made even if it had won the patent litigation.

123. In fact, Lupin knew that the No-AG Payment's value to it far exceeded $49 million, even setting aside the fact that the No-AG clause's term was for a year rather than a half-

year. Lupin knew and intended that its agreement to delay entry until 2016 would encourage Assertio/Santarus to exploit the market power that Lupin's agreement had secured for them. As set forth in further detail below (see Section VIIIA), Assertio/Santarus got that bought-and-paid-for monopoly into the hands of another brand manufacturer that was able to fully exploit it. That manufacturer—Valeant—used the generic-free time period to raise the price of branded Glumetza by nearly 800%, causing dollar sales to rise to more than $1.2 billion annually by 2016.

124. Thus, the No-AG Payment resulted in Lupin's making sales in the six-month period in 2016 of some $295 million. This is $280 million more than Lupin would have made by marketing the product for six months in 2012 with an authorized generic on the market. And, this estimate assumes that the No-AG clause's term was only six months rather than a year.

125. The No-AG Payment resulted in Assertio/Santarus's forgoing between $15 million and $30 million in sales of an authorized generic in 2012 (depending on whether the No-AG clause's term was six months or a year). But the No-AG Payment caused Lupin to delay entry into the market by nearly four years. That delay was worth more than $2.8 billion to Assertio/Santarus and their successors.

126. Assertio/Santarus's No-AG Payment to Lupin impaired competition in at least three ways. It: (a) allocated 100% of the Glumetza market to Assertio/Santarus for the period before generic competition; (b) allocated 100% of the generic segment of the market to Lupin for at least 180 days; and (c) substantially delayed entry by *all* generic manufacturers.

127. Had Assertio/Santarus not paid Lupin to drop its patent challenge and delay entry into the market, Lupin would have marketed its less expensive generic Glumetza: (a) "at-risk" (*i.e.*, while the patent litigation was pending) upon the expiration of the 30-month stay; (b) upon winning the patent litigation; or (c) earlier than February 1, 2016, on a date to be determined by a jury, pursuant to a lawful settlement agreement without a large unjustified payment from Assertio/Santarus to Lupin. Absent the No-AG Payment, immediately upon Lupin's entry into the market (or before), Assertio/Santarus, as a rational economic actor seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin, driving prices down even further.

128. Defendants have no procompetitive explanation or justification for the No-AG Payment. The large, unjustified payment had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation. Typical litigation costs for patent cases of this nature rarely exceed $5.5 million. Assertio/Santarus's future expected litigation costs at the time it unlawfully paid Lupin—after two years of patent litigation—were likely much less than that.

129. The No-AG Payment was anticompetitive and unlawful regardless of whether it constitutes a reverse payment.

E. Assertion/Santarus and Lupin Neutralized Competition from Later Filers.

130. The No-AG Payment significantly delayed competition by Lupin and deprived Glumetza purchasers of dramatically lower prices. But the potential for competition from other generic manufacturers remained. So Assertio/Santarus and Lupin included other anticompetitive provisions in their settlement to neutralize those potential threats.

131. As the first filer, Lupin was eligible to receive the 180-day ANDA Exclusivity. As described in detail above, however, Congress left open pathways for later-filer generic manufacturers cause forfeiture of the 180-day ANDA exclusivity and come to market before the entry date agreed between the first filer and the patent holder.

132. As applicable here, a later filer could get a final court decision that its generic Glumetza product did not infringe any of Assertio's valid patents. In that event, Lupin would forfeit its ANDA Exclusivity if it failed to enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). Having agreed to delay entry until February 1, 2016, it is likely that Lupin *would* fail to enter within 75 days, and therefore *would* forfeit, if a later filer got the final court decision before November 18, 2015. That forfeiture would allow the later filer to enter before Lupin. If Lupin forfeited its ANDA Exclusivity, additional later filers could enter before Lupin by winning their patent litigations or using the leverage of their patent challenges to get a license from Assertio/Santarus.

133. Here, it was overwhelmingly likely that a later filer would be able to cause forfeiture of Lupin's exclusivity. First, as described in detail above, Assertio's patents on

Glumetza were very narrow and could easily be designed around. Lupin could and did design around them simply by using a reservoir system rather than a matrix system. Assertio/Santarus and Lupin knew that other generic manufacturers could do the same thing.

134. Second, Lupin agreed to a very long delay in generic entry—nearly four years. As described in detail below, in February 2012 when Assertio/Santarus and Lupin agreed to their No-AG Payment, later filer Sun Pharmaceutical was well into its patent litigation with Assertio/Santarus. That litigation could reasonably be expected to be completed, through a final court decision, by no later than February 2015. Sun Pharmaceutical could therefore expect a very substantial reward, in the form of a year or more of exclusive or semi-exclusive sales in the generic sector, for getting onto the market before Lupin.

135. Assertio/Santarus and Lupin sought to deter such entry by including a Most Favored Entry ("MFE") clause and a Most Favored Entry Plus ("MFEP") clause in their agreement. The MFE provided that, if any other generic manufacturer succeeded in entering the market with generic Glumetza before Lupin's scheduled February 1, 2016 date, Lupin's entry would be moved up accordingly. The MFEP provided that Assertio/Santarus would not grant a license to any other manufacturer to enter the market with generic Glumetza until a date that was at least 180 days after Lupin entered.

136. Without the MFE and MFEP, Lupin faced a high likelihood that it would be stuck on the sidelines while later filers entered the market a year or more in advance and reaped the corresponding gains of being the first ANDA entrants.

137. Congress intentionally left open pathways for later filers to enter first and enjoy periods of exclusivity or semi-exclusivity. Those pathways created incentives for later filers to enter the market before a delayed entry date to which a first filer agreed. MFEs and MFEPs undermine those incentives. The MFE and MFEP agreed between Assertio/Santarus and Lupin ensured that later filers could not in fact benefit from the two pathways (litigation victory or better license) that Congress intentionally left open for later filers to improve on the entry date to which Lupin had agreed.

138. In short, Assertio/Santarus and Lupin's purpose in agreeing to the MFE and MFEP was to (1) deter later filers from trying to enter the market before Lupin's delayed February 2016 entry date; and (2) eliminate the threat that later filers would use the statutory procedures to cause the forfeiture of Lupin's ANDA Exclusivity, and (3) compensate Lupin for agreeing to a four-year delay. The MFE and MFEP deterred later filers from trying to enter the market before Lupin, in return for which Lupin agreed to later entry.

F. The MFE and MFEP Delayed Later Filers' Entry

139. Assertio/Santarus' and Lupin's anticompetitive scheme worked. The MFE and MFEP succeeded in preventing any other generic manufacturer from entering the market before Lupin's delayed entry date.

140. Sun Pharmaceuticals Industries Inc., Sun Pharmaceutical Industries Ltd., and Pharma Global FZE, (collectively, "Sun") filed the second ANDA seeking to market generic versions of Glumetza 500 mg and 1000 mg tablets before the expiration of the Orange Book-listed patents.

141. On or about May 6, 2011, Sun notified Assertio that Sun had filed ANDA 202917, detailing why its generic Glumetza did not infringe a valid claim of the relevant Orange Book patents.

142. On June 20, 2011, Assertio filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun asserting infringement of the '962, '340, '280, '475, and '987 patents listed in the Orange Book. Valeant International Bermuda ("VIB") joined in the lawsuit as a co-plaintiff because it owned the '987 patent and exclusively licensed it to Assertio. Assertio and VIB sued Sun within 45 days of receiving the paragraph IV certification, so the automatic 30-month stay prohibiting Sun's entry into the market started to run on or about May 6, 2011 and would expire on or about November 6, 2013.

143. Assertio also sued Sun for infringement of U.S. Patent No. 7,736,667 ("the '667 patent"), which is not listed in the Orange Book. The '667 patent discloses a dual-matrix, controlled-release oral dosage form. The first matrix—the "core"—is comprised of a water-swellable polymeric material "in which drug is dispersed." The second matrix—the "shell"—

forms a "casing that surrounds and fully encases the core." This shell is comprised of a water-swellable polymeric material "that swells upon imbibition of water (and hence gastric fluid) to a size large enough to promote retention in the stomach during the fed mode[.]" A drug employing a reservoir system does not, by definition, use a dual-matrix system with a core and shell that each swell upon imbibition of water. Thus, the '667 patent, like the other Glumetza patents, was not likely to pose a bar to a generic that uses a reservoir system.

144. Like Lupin before it, Sun denied that the relevant patents covered its ANDA product, asserting that its proposed generic tablet controlled the release of metformin using a reservoir system in which a drug core is covered by a polymeric membrane, rather than a matrix system claimed under the patents.

145. On January 25, 2013, Assertio/Santarus and VIB entered into an agreement that terminated Sun's challenge to the Glumetza patents. During the negotiations leading to that agreement, Sun learned that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Sun's incentive to continue its challenge. Consequently, Sun agreed that it would not begin selling a generic version of Glumetza until August 1, 2016—180 days after Lupin's delayed entry date.

146. It is unknown at the present time whether Assertio/Santarus made any payment to Sun to compensate it for agreeing not enter the market before August 2016.

147. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.–Florida, and Watson Pharma, Inc.(collectively "Watson") filed the third ANDA seeking to introduce generic Glumetza before expiration of the Orange Book patents. Initially, Watson filed an ANDA for only a 1000 mg product.

148. On or about March 7, 2012, Watson notified Assertio that Watson had filed ANDA 203755, detailing why its generic Glumetza 1000 mg would not infringe a valid claim of the relevant Orange Book patents.

149. On April 18, 2012, Assertio and VIB filed a lawsuit in the U.S. District Court for the District of Delaware against Watson for infringement of the patents listed in the Orange Book for Glumetza 1000 mg at the time the lawsuit was filed (the '962 and '987 patents). Assertio and

VIB sued Watson within 45 days of receiving the paragraph IV certification, and the automatic 30-month stay prohibiting Watson's entry into the market was to expire on or about September 7, 2014.

150. In February 2013, Assertio and VIB amended their complaint to add infringement of a newly listed Orange Book patent (the '692 patent), as well as two non-Orange Book listed patents (the '667 patent and U.S. Patent No. 8,329,215 ("the '215 patent")).

151. The '215 patent, like the '667 patent, discloses a dual-matrix system where a dosage form employs a core and shell that each swell upon imbibition of water. As explained above, a product using a reservoir system does not have such properties and so falls outside the scope of the '215 patent's claims.

152. On February 28, 2013, Assertio filed a new complaint in the U.S. District Court for the District of Delaware against Watson for infringement of the '962, '340, '280, '475 patents. Assertio filed the lawsuit in response to Watson's paragraph IV notice letter to Assertio, dated January 18, 2013, stating that Watson had amended its ANDA 203755 with the intent to market a generic version of Glumetza 500 mg tablets, in addition to the previously noticed 1000 mg tablets, before the relevant Orange Book-listed patents expired. The resulting automatic 30-month stay of Watson's generic Glumetza 500 mg product was not to expire until on or about July 18, 2015.

153. On November 8, 2013, Assertio/Santarus and VIB entered into an agreement that terminated Watson's challenge to the Glumetza patents. During the negotiations leading to that agreement, Watson learned that Assertio/Santarus had agreed to an MFE and MFEP with Lupin, which significantly diminished Watson's incentive to continue its challenge. Consequently, Watson agreed that it would not begin selling a generic version of Glumetza until August 1, 2016—180 days after Lupin's delayed entry date.

154. It is unknown at the present time whether Assertio/Santarus made any payment to Watson to compensate it for agreeing not enter the market before August 2016.

155. Absent the No-AG Payment to which Assertio/Santarus and Lupin agreed, and the MFE and MFEP included in that agreement, Sun and Watson would have entered the market

much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected more than $2.8 billion in branded Glumetza sales.

G. Defendants Fully Exploited The Monopoly They Created.

156. The Glumetza monopoly that Assertio/Santarus and Lupin created and maintained was a very valuable asset. They wasted no time in getting it into the hands of a commercial entity that mercilessly and ruthlessly exploited it, with devastating consequences for Glumetza purchasers.

157. In February 2012, Assertio/Santarus's price for branded Glumetza was more than five times what the competitive price would have been in a fully competitive generic sector. At that time, there were three potential means by which Glumetza purchasers could get relief from these high prices: entry by Lupin; entry by a Santarus authorized generic; or entry by later filers. The No-AG Payment between Assertio/Santarus and Lupin extended the Glumetza monopoly by four years rather than ending it, and compounded that injury by ensuring the absence of an authorized generic (whether sold by Santarus or a licensee) once Lupin belatedly entered the market. Assertio/Santarus and Lupin also agreed to the MFE and MFEP to ensure that no later filers would upend their anticompetitive scheme by entering the market with an ANDA generic before Lupin's delayed entry date. The No-AG Payment, MFE, and MFEP closed off every available avenue of generic competition. Rather than ending the Glumetza monopoly, those clauses ensured that it would extend for at least another four years.

158. That guaranteed four-year monopoly was enormously valuable, and Assertio/Santarus immediately cashed in on it by selling it to those who could more effectively exploit it. Through the anticompetitive conduct described above, Assertio/Santarus ensured that Lupin would not introduce generic Glumetza until February 2016, and Sun and Watson would not introduce generic Glumetza until August 2016. The last piece of the anticompetitive trifecta was the agreement that Assertio/Santarus and Watson announced on November 8, 2013.

159. On November 7, 2013, Defendant Salix announced that it had reached an agreement to acquire Santarus. Salix did not finally agree to the acquisition until it was assured

that Assertio/Santarus had reached a deal with Watson to delay marketing its generic Glumetza until August 2016. Salix's CEO reported to stock analysts that Salix was "comfortable" with the acquisition because Glumetza would not be "lost to generics" until 2016.

160. When Salix was negotiating the acquisition, Glumetza accounted for just under half of Santarus's annual sales. Under the acquisition agreement, Salix agreed to pay $2.6 billion for Santarus. That purchase price represented a 37% premium over Santarus's share price before the acquisition was announced.

161. Then Salix too cashed in on the Glumetza-monopoly sweepstakes. Just 13 months after acquiring Glumetza, in February 2015, Salix announced its acquisition by Valeant.

162. When Valeant acquired Salix in April 2015, Glumetza accounted for more than 25% of Salix's sales. Valeant paid $14.5 billion for the Glumetza monopoly and the other Salix assets.

163. The Glumetza monopoly was the perfect asset for Valeant to acquire. Valeant did not believe in developing new drugs for the betterment of patients. It believed in buying existing drug-product monopolies and exploiting them to the fullest extent. During the relevant time here, Valeant's annual Research and Development budget was less than 3% of its revenues, about a fifth of the pharmaceutical industry average. The motto of Valeant's CEO was "Don't bet on science—bet on management." And he called investing in pharmaceutical research "a losing proposition."

164. Valeant's board of directors implemented its "forget science, exploit existing monopolies" strategy by operating the company like a hedge fund and paying its executives as if they were hedge-fund managers. Valeant paid relatively little cash compensation to top executives, but granted them huge stock options that vested only if the company reached aggressive revenue goals.

165. Valeant reached those goals by acquiring companies like Salix that had existing drug-product monopolies. Valeant would then slash the workforce, especially the scientists, and take enormous price increases on already existing monopolized drugs. As Forbes magazine later characterized it, Valeant's strategy "emphasized boosting drug prices, gutting research and

development budgets, [and] firing employees." Vardi & Gara, *supra*. "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary." *Id.* Some pharmaceutical manufacturers may refrain from fully exploiting drug monopolies, based on their longer-term outlooks or concerns about public scrutiny. Valeant had no such qualms.

166. A former Valeant executive later described Valeant's culture: "We're the bad boys, we're successful, we can do whatever we want." McLean, *supra*. The CEO admitted publicly that "[a]ll I care about is our shareholders" and that, "from [an investor's] standpoint [raising prices] is not a bad thing." *Id.* Unsurprisingly, industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned." *Id.*

167. Glumetza purchasers were among the "every other consideration" that Valeant scorned. Immediately after acquiring the Glumetza monopoly, Valeant applied its corporate strategy of fully exploiting existing monopolies. Valeant bought the Glumetza monopoly from Salix in April 2015. By the end of July 2015, Valeant had raised the price of a 30-day supply by more than 750%, from $350 to more than $3,000. As a result, Valeant's revenues from Glumetza in the two quarters after the price increase skyrocketed from $145 million to more than $818 million.

168. Glumetza's massive price increase was made possible only by the unlawful agreements that delayed Lupin's generic entry to 2016. Valeant's price hike worked solely because a generic had not already entered the market and taken the unit sales at dramatically lower prices. Absent the No-AG Payment, Lupin would have begun marketing generic Glumetza long before Valeant's acquisition of Salix, as early as May 2012. Lupin's earlier entry thus would have deprived Valeant and anyone else of the opportunity to exploit the Glumetza monopoly.

169. Valeant's exploitation of the Glumetza monopoly and other drug-product monopolies drew the attention of the U.S. Congress, which held a number of hearings into Valeant's strategy of forsaking science in favor of price increases on existing drug-product monopolies. The hearings established that Valeant set drug prices to reach pre-determined revenue goals, and "sought to exploit [its] temporary monopol[ies] by increasing prices

dramatically to extremely high levels very quickly." House Comm. On Oversight and Government Reform Memorandum, *Documents Obtained by Committee from Valeant Pharmaceuticals* (Feb. 2, 2016), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on% 20Valeant%20Documents0.pdf.

170. In a February 4, 2016 hearing, Representative Cummings specifically highlighted Valeant's exploitation of the Glumetza monopoly, noting that Valeant raised its price "by a whopping 800 percent over a mere six-week period." *Developments in the Prescription Drug Market: Oversight Hearing Before the House Comm. On Oversight and Government Reform*, 114 Cong., at 3, 119 (Feb. 4, 2016), *available at* https://www.govinfo.gov/content/pkg/CHRG-114hhrg25500/pdf/CHRG-114hhrg25500.pdf. He noted that Valeant's "basic strategy has been to buy drugs that are already on the market and then raise the prices astronomically [for a] temporary period of time before other competitors enter the market." *Id*.

171. In order to placate Congress, Valeant's CEO testified to the U.S. Senate on April 27, 2016 that "it was a mistake to pursue, and in hindsight I regret pursuing, transactions where a central premise was a planned increase in the prices of the medicines." Statement of J. Michael Pearson before the Senate Special Committee on Aging (Apr. 27, 2016), https://www.aging.senate.gov/imo/media/doc/SCA_Pearson_4_27_16.PDF. And he gave them the false comfort that, going forward, "[w]e expect our pricing actions to track industry norms." *Id*.

172. Yet, at that very moment, Valeant was continuing to adhere to the unlawful agreements that extended the Glumetza monopoly. In February 2016, two months earlier, Defendant Lupin had finally entered the market with generic Glumetza in accordance with its unlawful agreement to keep generic Glumetza off the market until February 2016.

173. By then, Valeant's ruthless exploitation of the Glumetza monopoly had raised the price of the branded product astronomically. And when Lupin entered the market, Valeant adhered to the unlawful agreement by refraining from marketing an authorized generic.

174. The direct result of that unlawful adherence was that Lupin, as the only generic available, was able to price its generic at a substantially smaller discount off the brand price than

it otherwise would have. As a result, Lupin was able to take advantage of the gigantic price increases for Glumetza that the Defendants engineered. Lupin's agreement to delay entry by four years allowed Valeant to raise the brand price by nearly 800%. And once Lupin finally entered, Valeant adhered to its unlawful agreement with Lupin not to market an authorized generic, which would have driven the generic price down to a 48% discount off the brand price. While Valeant was mollifying Congress with false assurances that Valeant had reformed its corporate ways, it was both keeping its brand price at the monopoly-enabled level and depriving purchasers of the generic competition that would have cut then-current prices in half.

175. As a result, throughout 2016, the price of Glumetza was more than $3,000 per month and the price of Lupin's generic Glumetza was more than $2,200 per month. Had Defendants not entered into their unlawful agreements, these prices would have been substantially lower. Lupin would have entered the market in 2012, Assertio/Santarus would have immediately entered the market with an authorized generic, and later both Sun and Watson would have entered with their generics.

176. In 2012, the price of a 30-day supply of 1000 mg branded Glumetza was about $250. By the beginning of 2015—long before Valeant got its hands on the product and jacked up prices by more than 750%—the generics would have taken almost all of the unit sales and would have competed the price of a 30-day supply down to about $55.

177. As a result of the delay in generic entry and the Defendants' full exploitation of the monopoly that the delay created, only the branded product was available in 2015. And, the price of a 30-day supply of brand Glumetza after Valeant's increase was more than $3,000 rather than about $55, the price at which generic Glumetza was likely to have sold for had it been available earlier. Lupin belatedly entered the market in 2016. But the combined effect of the astronomical brand price and Valeant's agreement not to market an authorized generic was that Lupin's price for a 30-day supply of the generic product was more than $2,200 rather than about $55, the price at which Glumetza was likely to have sold for had it been available earlier.

178. Altogether, Defendants' unlawful extension of the Glumetza monopoly has already caused more than $2.8 billion in total overcharges to direct purchasers, including McKesson.

And, it continues to cause substantial overcharges today (and will continue to do so for the foreseeable future to) at the rate of more than $175 million every year.

179. On May 15, 2017, Teva Pharmaceutical Industries Ltd. (which had acquired Watson) began marketing its generic Glumetza 500 mg and 1000 mg. On July 25, 2018, Sun began marketing its generic Glumetza 500 mg and 1000 mg. Watson and Sun had received licenses from Assertio/Santarus to enter the market in August 2016. The reasons for their delays after August 2016 are currently unknown.

180. Defendants' anticompetitive conduct caused Watson and Sun to agree to delay their generic entry until August 2016. As a result, they could put development of their generic Glumetza on hold. If Defendants had not caused Watson and Sun to agree to delay entry until August 2016, they would have resolved any technical or other issues that delayed their actual entry much sooner (or they never would have encountered them to begin with). Absent Defendants' conduct, Watson and Sun were like to enter the market before July 2015, on a date to be determined by the jury.

VI. INTERSTATE COMMERCE

181. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. MARKET EFFECTS

182. By impeding competition from generic Glumetza, Defendants' anticompetitive conduct caused Plaintiff and its indirect assignor McKesson to pay more than they would have paid for branded and generic Glumetza. Earlier entry of Lupin's generic Glumetza would have given purchasers the choice between branded Glumetza and AB-rated generic substitutes for Glumetza, which would have been priced substantially below the brand. Many purchasers would have bought the lower-priced generic Glumetza rather than the higher-priced branded Glumetza. Every state's pharmacy substitution laws require or encourage pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent the Defendants' anticompetitive conduct, Plaintiff and McKesson would have saved hundreds of millions of

dollars by paying less for branded Glumetza and purchasing generic Glumetza earlier. Defendants' anticompetitive conduct caused Plaintiff to incur overcharges on their purchases of both branded and generic Glumetza.

183. Absent the Defendants' anticompetitive conduct, immediately upon Lupin's entry into the market, Assertio/Santarus, as a rational economic actor, would have sold authorized generic Glumetza in competition with Lupin. As described in detail above, Santarus had a history of marketing authorized generics. And, Santarus specifically negotiated with Assertio for the right to market an authorized generic version of Glumetza.

184. The economic rationality of marketing an authorized generic (absent an unlawful No-AG pact) is confirmed by Valeant's conduct. Through its subsidiary Oceanside, Valeant frequently markets authorized generics when its branded drugs first experience generic competition. It did so with respect to its drugs Syprine, Mephyton, Uceris, Xenazine Tabs, Vanos, and Retin-A Micro. Indeed, Valeant began marketing an authorized generic version of Glumetza in February 2017, after its No-AG pact with Lupin expired.

185. After Valeant's authorized generic entered the market, Lupin's CEO admitted that "[t]he authorized generic was a pretty tough competitor for us to have and that brought the pricing down for the entire market." Absent the unlawful No-AG Payment, the substantial price decreases attendant upon an authorized generic would have occurred sooner and simultaneously with (or before) Lupin's earlier entry into the market.

186. Defendants' MFE and MFEP compounded the No-AG Payment's anticompetitive effects. The MFE and MFEP discouraged Sun and Watson from seeking to enter the market before the entry date that Assertio/Santarus paid Lupin to accept. Those anticompetitive clauses undermined the incentives that Congress provided for Sun, Watson, and other potential competitors to enter the market before Lupin's unlawfully agreed February 2016 entry date. Absent the MFE and MFEP, Sun and Watson would have entered the market much sooner than they did, well before 2015.

187. Defendants' anticompetitive conduct created and extended the Glumetza monopoly. Absent Defendants' anticompetitive conduct, Lupin would have begun marketing

generic Glumetza before Valeant's April 2015 acquisition of the Glumetza monopoly, as soon as May 2012. The mid-2015 price increases on branded Glumetza never would have occurred.

188. Absent Defendants' unlawful conduct, Lupin would have entered the market in or about 2012, when the brand price for a 30-day supply of 1000 mg Glumetza was $250. Long before 2015, generic competition would have driven the price down to about $55.

189. As a result of the delay in generic entry and Defendants' full exploitation of the monopoly that the delay created, only the branded product was available in 2015, and the monthly price for 1000 mg Glumetza after Valeant's price increases was more than $3,000. That price was more than 50 times greater than it would have been if the Defendants had not delayed and impaired generic competition. Plaintiff also incurred substantial overcharges from 2012 until the gigantic price increases in 2015, and they continue to incur ongoing and accumulating overcharges today.

190. Defendants' unlawful conduct also harmed Plaintiff by increasing the prices charged by Glumetza generics. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent Defendants' unlawful conduct, the generics would have entered in or about 2012, when the price for a 30-day supply of 1000 mg brand Glumetza was about $250 rather than $3,000. Thus, Defendants' unlawful conduct has caused Plaintiff to pay substantial overcharges on purchases of Glumetza generics, beginning in February 2016 and continuing until today.

VIII. MONOPOLY POWER AND MARKET DEFINITION

191. At all relevant times, Defendants Assertio/Santarus, Salix and Bausch had substantial market power in the market for Glumetza and its generic equivalents. Defendants had the power to maintain the prices of those drugs at supracompetitive levels without losing sufficient sales to other products to make the supracompetitive prices unprofitable.

192. A small but significant and non-transitory increase in the price of brand Glumetza, above the competitive level would not cause a significant loss of sales to any product other than AB-rated versions of Glumetza. At competitive prices, brand Glumetza does not exhibit

significant, positive cross-elasticity of demand with respect to price with any product or treatment for diabetes other than AB-rated generic versions of Glumetza.

193. Direct evidence of Defendants' market power includes the following: (a) absent Defendants' unlawful conduct, generic Glumetza would have entered the market much earlier at a substantial discount to brand Glumetza; (b) when generic Glumetza eventually entered the market, it quickly took a substantial portion of brand Glumetza's unit sales; (c) Defendants' gross margin on Glumetza (including the costs of ongoing research/development and marketing) at all relevant times was in excess of 70%; (d) Defendants never lost Glumetza sales or lowered the price of Glumetza to the competitive level in response to the pricing of other brand or generic drugs; (e) from 2012 to 2015, Defendants profitably raised the price of Glumetza by more than 40%; and (f) in 2015 Defendants profitably raised the price of Glumetza by more than 750%.

194. At all relevant times, Defendants had monopoly power in the market for Glumetza and AB-rated generic substitutes because they had the power to exclude competition and/or raise or maintain the price of Glumetza to supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

195. The existence of other branded diabetes drug products did not constrain the price of Glumetza to the competitive level. Defendants needed to control only Glumetza and its AB-rated generic equivalents, and no other products, in order to maintain the price of Glumetza at supracompetitive prices. Only the market entry of a competing, AB-rated version of Glumetza could prevent Defendants from profitably maintaining prices at supracompetitive levels.

196. Glumetza is therapeutically differentiated from other diabetes products. In general, metformin is considered the first-choice medication for the treatment of Type 2 diabetes and is not reasonably interchangeable with other Type 2 diabetes drugs. In part, this is the result of metformin's long-term safety profile, which is not available for many newer Type 2 diabetes drugs such as DPP-4 inhibitors. Metformin also has better cardiovascular mortality than sulfonylurea drugs used to treat Type 2 diabetes. Metformin is also considered weight neutral or helps people lose weight.

197. Glumetza is not therapeutically interchangeable with metformin products that are unavailable in an extended-release form. Metformin can cause gastrointestinal side effects, which can be reduced by taking an extended-release form. Additionally, extended-release forms of metformin can reduce the daily dosing to a single once-a-day pill providing a simpler dosing regimen. The differing efficacy, dosing, safety and side-effect profiles of different oral Type 2 diabetes drugs play a critical role in doctors' selection of the most appropriate form of the drug for each patient, and a patient's compliance with taking an oral Type 2 diabetes drug is improved with one that requires fewer doses and that the patient can better tolerate.

198. Glumetza is not reasonably interchangeable with other extended-release forms of metformin such as Glucophage XR and Fortamet. This non-interchangeability arises from, among other reasons, the way that different patients react to the products' varying release mechanisms.

199. Specifically, a substantial number of doctors perceive Glumetza to offer the possibility of reduced gastrointestinal side effects for patients, compared to other extended-release metformin products. Glumetza uses a polymer delivery technology that expands from stomach fluid, preventing the pill from moving into the intestine. The stomach fluid then dissolves and releases the metformin over a period of 8 to 10 hours. The dissolved metformin is thus mixed, over time, with other contents of the patient's stomach and transported into the duodenum, where it is absorbed.

200. This process results in some substantial number of doctors concluding that Glumetza may cause fewer gastrointestinal side effects than other extended-release metformin products. Assertio/Santarus, Salix, and Valeant differentiated Glumetza from extended-release metformin products in their marketing, on the ground that it retains metformin in the patient's stomach, allowing for constant multi-hour flow of the drug into the gastrointestinal tract. And they asserted that this technology offered patients a significantly enhanced opportunity for increased absorption of the drug. They touted to investors and others that "physicians are receptive to Glumetza's differentiating features of controlled delivery and GI tolerability." Moreover, the extended-release mechanism dissolves at the end of its useful life and is passed through the gastrointestinal tract and eliminated.

201. In contrast, another extended-release metformin prescription drug—Fortamet—delivers metformin throughout the entire gastrointestinal tract. Fortamet tablets have a membrane surrounding the metformin, and the membrane has two laser-drilled holes. Water is taken into the holes and dissolves the metformin inside, and the dissolved drug is released through those holes at a constant rate all the time that the pill is moving through the small intestine. Some substantial number of doctors conclude, therefore, that Fortamet has a higher likelihood of causing gastrointestinal side effects. And patients typically will see the pill's shell in their stool.

202. Very substantial decreases in the price of other extended-release metformin products did not constrain the price of brand Glumetza to the competitive level. For example, generic Fortamet entered the market in 2012, substantially driving down the average price of a Fortamet pill (weighted average of brand and generic price). Despite that substantial price decrease, from 2012 to mid-2015, the quarterly unit sales of Glumetza increased while the price increased more than 40%. The percentage increase in Glumetza net revenue (net of all discounts, rebates, etc.) was at least that great.

203. A generic version of another extended-release metformin product—Glucophage XR—has been available since 2005. That product's extended-release mechanism is similar to Fortamet's and dissimilar to Glumetza's. Yet from 2012 through mid-2015 Glumetza had the sales, price, and net revenue gains described above.

204. Neither Glucophage XR (brand or generic) nor Fortamet (brand or generic) prevented the nearly 800% price increase in Glumetza in 2015. That price increase was enormously profitable for Valeant. The dollar sales of brand Glumetza for the third and fourth quarters of 2015 (after the price increase but before Lupin's entry) were more than $800 million; the sales in the prior two quarters were less than $145 million.

205. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant antitrust product market is the market for Glumetza and its AB-rated generic equivalents.

206. At all relevant times, Defendants were protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician

detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or may assertedly be covered by patents or other forms of intellectual property. Defendants' unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants lacked the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reduced output.

207. The relevant geographic market is the United States.

208. Defendants Assertio/Santarus', Salix's and Bausch's market share in the relevant market was 100% until Lupin's entry in 2016, implying substantial market power.

IX. TOLLING AND FRAUDULENT CONCEALMENT

209. By virtue of its assignments, Plaintiff is a member of the putative class on whose behalf a class action was filed on August 29, 2019. *See FWK Holdings, LLC v. Bausch Health Cos., Inc. et al.*, Case No. 3:19-cv-05426-WHA (N.D. Cal.). The filing of that action tolled the statute of limitations applicable to Plaintiff's assigned claims. Antitrust plaintiffs obtain a cause of action each time they purchase a product at a price that is higher than it would otherwise be as a result of an antitrust violation. Thus, without the benefit of any tolling doctrine other than class action tolling, Plaintiff is entitled to recover overcharges on purchases made within the four years prior to the filing of the *FWK Holdings* case—*i.e.*, on all purchases of branded or generic Glumetza made on or after August 30, 2015.

210. Plaintiff is also entitled to recover overcharges on purchases made prior to August 30, 2015 because Defendants fraudulently concealed their antitrust violations; Plaintiff did not discover those violations until a date within four years of the filing of this action; and Plaintiff could not have discovered those violations earlier through the exercise of reasonable diligence.

211. Defendants' scheme was inherently self-concealing, and Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

212. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff. Defendants repeatedly made public reference to Lupin's agreement to delay entry until February 2016, but consistently, consciously, and actively omitted the fact that Lupin had agreed to that delayed date in exchange for a No-AG Payment. For example:

a. In a May 8, 2012 filing with the Securities and Exchange Commission ("SEC"), Assertio included a redacted copy of its settlement agreement with Lupin. Assertio redacted all references to the No-AG Payment. Based solely on information received and events occurring within the last four years, Plaintiff now believes that the redacted agreement refers to the No-AG Payment as follows:

"Section 3.5. [***]

Section 3.6. [***] Notwithstanding the provisions of Sections 3.4 and 3.5, Depomed and Santarus shall have the right to: [***]"

b. On March 27, 2012, pursuant to their settlement Assertio and Lupin asked this Court to enter a consented-to injunction in the patent litigation. Those Defendants falsely represented to this Court—and placed on the public record—that the terms of their settlement were in "good faith," "serve the public interest," were "procompetitive," and "benefit … the parties and consumers alike." Consent Injunction and Dismissal Order, *Depomed, Inc. v. Lupin Pharmaceuticals, Inc., et al.,* No. 4:09-cv-05587-PJH, ECF No. 152, at p. 1 (March 27, 2012). Those Defendants affirmatively advised the Court and the public of the agreed entry date of February 1, 2016 but omitted all references to the No-AG Payment. *See id*. at 5(a).

c. In the following SEC filings, Santarus affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Santarus Inc., Annual Report (Form 10-K), at 24 (March 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (May 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (August 7, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (November 8, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 34 (November 7, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 13 (May 6, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 14 (August 6, 2013).

d. In the following SEC filings, Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 9 (March 1, 2013); Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 7 (February 28, 2014).

e. In addition to the May 8, 2012 SEC filing discussed above, Assertio (formerly known as Depomed, Inc.) affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment: Depomed Inc., Annual Report (Form 10-K), at 5 (March 8, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 22 (August 3, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 24 (November 5, 2012); Depomed Inc.,

Quarterly Report (Form 10-Q), at 21 (November 9, 2013); Depomed Inc., Quarterly Report (Form 10-Q), at 21 (August 8, 2013); Depomed Inc., Quarterly Report (Form 10-Q), at 23 (November 7, 2013).

f. In a call with stock analysts on May 8, 2012, Assertio affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment.

g. In a press release dated May 8, 2012, Santarus affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment.

h. In calls with stock analysts on November 7, 2013 and January 16, 2014, Salix affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment.

i. In a call with stock analysts on October 27, 2015, Lupin affirmatively referred to the agreed February 2016 entry date, but omitted all references to the No-AG Payment.

213. Defendants did not publicly disclose the No-AG Payment until doing so suited their interests. Specifically, Lupin was trying in a February 5, 2016 call with stock analysts to pump up the value of its stock. To emphasize that it would make extraordinary profits on the sale of generic Glumetza, Lupin revealed publicly for the first time that the settlement agreement included a No-AG pact. Plaintiff have filed this Complaint within four years of that first public revelation of the No-AG Payment.

214. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by Defendants, Plaintiff had no knowledge of the scheme and conspiracy more than four years before the filing of this Complaint; did not have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if it had been in possession of facts or information to cause them to conduct an investigation, any such investigation would not have revealed the existence of Defendants' unlawful conspiracy.

215. Plaintiff lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of Plaintiff would not have uncovered those facts more than four years before the filing of this complaint.

216. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's claims have been tolled.

X. IMPACT AND CONTINUING INJURY TO PLAINTIFF

217. During the relevant period, Plaintiff and McKesson purchased substantial quantities of brand and generic Glumetza at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and McKesson were compelled to pay, and did pay, artificially inflated prices for their requirements of Glumetza and its AB-rated generic equivalents. Those prices were substantially greater than the prices that would have been paid absent the illegal conduct alleged herein, because: (1) the price of Glumetza was artificially inflated by Defendants' illegal conduct; (2) Plaintiff was deprived of the opportunity to purchase lower-priced generic versions of Glumetza, which it would have done had it had the opportunity; and (3) when it ultimately became available, the price of generic Glumetza was higher than it would have been absent Defendants' unlawful conduct.

218. As a direct consequence of Defendants' antitrust violations, Plaintiff has sustained substantial loss and damage to its business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

219. As a result of Defendants' unlawful conduct, Plaintiff and McKesson continue to pay overcharges today, notwithstanding the launch of generic Glumetza in 2016. The commencement of generic competition does not immediately create a competitive environment that is indistinguishable from the environment that would have existed had generic competition begun much earlier. In fact, it can take considerable time for the process of generic competition to eliminate the effects of prior anticompetitive conduct, for several reasons, all of which apply here.

220. First, generic substitution rates do not immediately reach their maximum level when an AB-rated generic drug is launched. While generic substitution by Plaintiff typically reaches a level of 90% in approximately three months, generic substitution rates continue to increase gradually and incrementally after that time and eventually reach 95% or more, at which point they plateau. It may take a year or longer for generic substitution rates to reach this maximum level. Until they do, the actual generic substitution rate will be lower than it would have been had generic entry occurred earlier and Plaintiff (or McKesson) will continue to

purchase units of the branded drug that would have been replaced with units of the less expensive generic drug but for the antitrust violation. Generic substitution of generic Glumetza for branded Glumetza has not yet reached this maximum level.

221. Second, generic prices do not immediately drop to the level they would have achieved had generic competition begun earlier. Generic prices typically fall over time even in the absence of additional generic entrants so long as the number of generic manufacturers in the market does not decrease. In this case, generic prices were extraordinarily high after Lupin's belated launch in 2016, both because of the steep price increases on brand Glumetza and because Lupin did not face competition from an authorized generic (a direct result of Defendants' illegal conspiracy). Even after additional generics entered the market, generic prices have remained relatively high and continue to remain relatively high today. Had generic competition begun much earlier, as it would have absent Defendants' unlawful conduct, inter-generic competition would have been underway for a longer period of time and generic prices would have fallen to lower levels than the generic prices Plaintiff (or McKesson) are paying today.

222. The fact that generic substitution rates and generic prices can take considerable time to reach the equilibrium levels they would have reached had generic competition begun earlier means that Plaintiff will continue to pay overcharges on their purchases of branded and generic Glumetza for some time to come.

223. Plaintiff's injury is ongoing. Defendants' conduct threatens continuing loss and damage to Plaintiff unless enjoined by this Court.

XI. CLAIMS FOR RELIEF

CLAIM ONE: VIOLATION OF 15 U.S.C. § 1 (ALL DEFENDANTS)

224. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 223 above. This claim is asserted against all Defendants.

225. Defendants violated 15 U.S.C. § 1 by entering into and adhering to a contract, combination or conspiracy in unreasonable restraint of trade, namely the agreement to make a

reverse payment—the No-AG Payment—in exchange for Lupin's delaying its generic Glumetza until February 1, 2016, and to allocate the market for branded and generic Glumetza.

226. At all relevant times, Defendants Assertio/Santarus, Salix and Bausch individually and/or collectively had substantial market power with respect to sales of Glumetza and its AB-rated generic equivalents in the United States.

227. On or about February 22, 2012, Defendants entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Assertio/Santarus, Salix, and Bausch agreed to pay, and paid, Lupin substantial consideration in exchange for Lupin's agreement to delay bringing its generic version of Glumetza to the market, the purpose and effect of which were to: (a) delay generic entry of Glumetza in order to lengthen the period in which brand Glumetza would make supracompetitive profits; (b) keep an authorized generic off the market during Lupin's 180-day ANDA Exclusivity period, or longer, thereby allowing Lupin to charge supracompetitive prices and make supracompetitive profits on sales of generic Glumetza; (c) delay the date that other generic manufacturers would enter the market; and (d) raise and maintain the prices that Plaintiff would pay for Glumetza and its AB-rated equivalents at supracompetitive levels.

228. There is and was no legitimate, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the No-AG Payment was not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects on direct purchasers, competition, and consumers.

229. As a direct result of Defendants' violation of 15 U.S.C. § 1, Plaintiff has been injured, and absent injunctive relief will continue to be injured, in their business or property. Plaintiff's injury consists of having paid higher prices for their Glumetza requirements, and continuing to pay higher prices, than it would have paid in the absence of the violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

CLAIM TWO: VIOLATION OF 15 U.S.C. § 2
(ASSERTIO, SANTARUS, SALIX AND BAUSCH)

230. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 223 above. This claim is asserted against Assertio, Santarus, Salix and Bausch.

231. Defendants Assertio/Santarus, Salix and Bausch violated 15 U.S.C. § 2 by monopolizing the market for Glumetza and its AB-rated equivalents in the United States.

232. At all relevant times, Defendants Assertio/Santarus, Salix and Bausch possessed substantial market power (i.e., monopoly power) with respect to Glumetza and its AB-rated equivalents. Those Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

233. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

234. As alleged extensively above, Defendants Assertio/Santarus, Salix and Bausch willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen, and injured Plaintiff thereby.

235. It was those Defendants' conscious objective to further their dominance through exclusionary conduct.

236. As stated more fully above, those Defendants knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by entering into and abiding by the reverse payment agreement/No-AG pact with Lupin.

237. The purpose and effect of those Defendants' conduct was to maintain monopoly power that would otherwise have been eliminated through normal competitive processes, in violation of Section 2 of the Sherman Act.

238. To the extent that Defendants are permitted to assert one, there is and was no cognizable, procompetitive justification for their exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Defendants were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

239. Plaintiff has been injured, and absent injunctive relief will continue to be injured, in its business and property as a result of Defendants' monopolization in violation of Section 2 of the Sherman Act. Plaintiff's injury consists of having paid higher prices for their Glumetza requirements, and continuing to pay higher prices, than it would have paid in the absence of the violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

CLAIM THREE: VIOLATION OF 15 U.S.C. § 2
(ALL DEFENDANTS)

240. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 223 above. This claim is asserted against all Defendants.

241. Defendants violated 15 U.S.C. § 2 by conspiring to monopolize the market for Glumetza and its AB-rated equivalents in the United States.

242. At all relevant times, Defendants Assertio/Santarus, Salix and Bausch possessed substantial market power (i.e., monopoly power) with respect to Glumetza and its AB-rated equivalents. Those Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

243. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

244. As alleged extensively above, all Defendants willfully conspired to maintain that monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen, and injured Plaintiff thereby.

245. It was Defendants' conscious objective and specific intent to further their dominance through exclusionary conduct.

246. As stated more fully above, Defendants knowingly, willfully, and wrongfully conspired to maintain monopoly power and harm competition by entering into and abiding by the reverse payment agreement/No-AG pact.

247. The purpose and effect of Defendants' conspiracy was to maintain monopoly power that would otherwise have been eliminated through normal competitive processes, in violation of Section 2 of the Sherman Act.

248. To the extent that Defendants are permitted to assert one, there is and was no cognizable, procompetitive justification for their exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Defendants were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

249. Plaintiff has been injured, and absent injunctive relief will continue to be injured, in their business and property as a result of Defendants' conspiracy to monopolize in violation of Section 2 of the Sherman Act. Plaintiff's injury consists of having paid higher prices for its Glumetza requirements, and continuing to pay higher prices, than it would have paid in the absence of the violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff respectfully requests entry of judgment against Defendants and the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiff's overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiff's costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XIII. JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: February 18, 2020

Respectfully submitted,

/s/ Anna T. Neill

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